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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,623	09/19/2001	J. Christopher Flaherty	59249-020 (INSL-117)	1126

7590

12/02/2003

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EXAMINER
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HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/02/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/955,623

Applicant(s)

FLAHERTY, J. CHRISTOPHER

Examiner

Michael J Hayes

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 9-14, 16, 17, 19-22 and 24-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8, 15, 18 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of invention 1, species 1 shown in Fig. 3 in Paper No. 15 is acknowledged.

Claims 4-6, 9-14, 16-17, 19-22, and 24-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim at this time. Election was made **without** traverse in Paper No. 15. Claim 1 appears to be generic to withdrawn claims 4-6, 9-14, 16, 17, and 19-22 and if claim 1 is allowed in generic form, these withdrawn claims would be considered.

### ***Information Disclosure Statement***

The information disclosure statement filed 12/13/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed 11/25/02 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. There is no explanation of documents DE 4200595 and DE19920896. These references have not been considered.

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the embodiment of the dispenser coupled to the plunger must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements or structural relationships, such omission amounting to a gap between the elements or the necessary structural connections. See MPEP § 2172.01. The omitted elements or structural connections are: those required in order to have the plunger move in only a single direction on the lead screw.

Art Unit: 3763

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-3, 7, 8, 15, 18, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by CHOI (U. S. Patent No. 5,993,423). Choi discloses a device for delivering a fluid to a patient including a reservoir, threaded lead screw with plunger thereon which rotates with respect to the screw, but not a side wall of the reservoir, having a plunger insert 50,150, motor connected to the lead screw and a transcutaneous access tool connected to an exit port. (See figs. 1-3, 7, 8, 18, 20-22). Fig. 22 shows the insert and plunger made from different materials.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. MOBERG et al. (U. S. Patent No. 6,485,465) shows an infusion with a plunger coupled to a lead screw.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

mjh  
22 November 2003



**MICHAEL J. HAYES  
PRIMARY EXAMINER**